U.S. Department of Justice

United States Attorney
Southern District of New York

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September 12, 2013

BY FACSIMILE (212) 805-7986
Hon. Paul G. Gardephe
United States District Judge
United States Courthouse
40 Foley Square
New York, NY 10007

Re: *United States v. Novartis*, No. 11 Civ. 0071 (PGG)

D+F

Dear Judge Gardephe:

We write in response to Novartis's letter dated September 9, 2013 informing the Court of its intention to file a motion to dismiss the Government's amended complaint, and requesting a stay of discovery pending a decision on the motion to dismiss. For the reasons set forth below, Novartis's proposed motion to dismiss is without merit, and its request for a stay of discovery should be denied.

1. The Amended Complaint Satisfies Rule 9(b).

The amended complaint alleges a fraudulent scheme pursuant to which Novartis paid kickbacks to doctors in the form of honoraria and other benefits (collectively, "honoraria") in connection with sham speaker programs to induce the doctors to write prescriptions for its drugs. Am. Compl. ¶¶ 1-2. While Novartis seeks to portray the Government's allegations regarding this scheme as encompassing only a few "discrete examples" of violations of "internal policies," Def. Ltr. 3, the amended complaint alleges far more. It describes numerous doctors who reportedly spoke and/or took turns speaking on the same topic to the same individuals, *id.* ¶¶ 95-120; numerous doctors who reportedly attended the same speaker programs with the same individuals, *see id.*; numerous doctors who attended speaker programs at which there was no legitimate presentation, *see id.*; numerous doctors who were reported as having spoken at and/or attended speaker programs that they did not actually attend, *id.* ¶¶ 138-44; and numerous doctors who were treated to opulent meals, received other inappropriate perks and/or attended events at locations that were not conducive to a legitimate educational event, *id.* ¶¶ 121-34. These examples include well over 50 different doctors located in more than 15 states. *See id.* ¶¶ 97-144.

The amended complaint further alleges that the kickbacks had their intended effect — they led doctors to write prescriptions for Novartis drugs. *Id.* ¶¶ 3, 145-58. To support these allegations, the amended complaint cites Novartis's own "return on investment" analyses. *Id.* ¶¶

145-48. It also identifies 11 doctors who received honoraria in connection with sham speaker programs, and shows that those 11 doctors not only wrote prescriptions for specific Novartis drugs after they began receiving honoraria (or significantly increased levels of honoraria) in connection with those drugs, but also that they substantially increased their prescription writing during that period. *Id.* ¶¶ 153-54, 157. In addition, the amended complaint identifies two other doctors whose prescription writing for specific Novartis drugs skyrocketed after they began receiving honoraria (or significantly increased levels of honoraria) in connection with the drugs. *Id.* ¶¶ 151-52, 155. For example, one of those doctors went from writing an average of 0.5 prescriptions of Lotrel per month in the more than three years before he began receiving honoraria in connection with Lotrel to an average of 59.0 prescriptions per month in the approximately two years during which he received such honoraria. *Id.* ¶ 151. The amended complaint further alleges that doctors who received honoraria in connection with specific Novartis drugs — such as Lotrel, Valturna and Starlix —wrote higher levels of prescriptions not only for those drugs but for the company's drugs in general. *Id.* ¶¶ 158, 174. The amended complaint identifies two additional doctors (and three doctors in total) to whom this allegation specifically applies. *Id.* ¶ 158. Finally, for the 15 doctors identified in the amended complaint, the Government identifies each of the many prescriptions they wrote that were paid for by federal programs during the period they received honoraria (or significantly increased levels of honoraria). *Id.* ¶ 176 & Exs. A-O. These allegations are more than sufficient to satisfy Rule 9(b), which in the context of the False Claims Act ("FCA") requires only that the plaintiff allege "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009); *see U.S. ex rel. Assocs. Against Outlier Fraud v. Huron Consulting Grp.*, No. 09-1800, 2011 WL 253259, at *2 (S.D.N.Y. Jan. 24, 2011) (citing *Kanneganti*).

Novartis's arguments as to why the amended complaint fails to satisfy Rule 9(b) lack merit. *First*, contrary to Novartis's suggestion, the Government was not required to specifically identify more than 15 doctors who were involved in the fraud to support its allegation of a far-reaching fraudulent scheme. *Cf.* Def. Ltr. 1-2. Indeed, courts have specifically approved what the Government has done here: plead a complex and far-reaching fraudulent scheme with examples illustrative of the scheme. *See U.S. ex rel. Bledsoe v. Cmty. Health Sys.*, 501 F.3d 493, 510 (6th Cir. 2007); *see also In re Cardiac Devices Qui Tam Litig.*, 221 F.R.D. 318, 333 (D. Conn. 2004) ("where the alleged fraudulent scheme involved numerous transactions that occurred over a long period of time, courts have found it impractical to require the plaintiff to plead the specifics with respect to each and every instance of fraudulent conduct"); *U.S. ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 49 (D. Mass. 2001) (where allegations are "complex and far-reaching, pleading every instance of fraud would be extremely ungainly, if not impossible").

Second, the Government's allegations are sufficient to satisfy the causation requirement of Rule 9(b). *Cf.* Def. Ltr. 2. As discussed above, Rule 9(b) requires only that the Government plead with particularity allegations of a fraudulent scheme sufficient to support a strong inference that false claims were submitted to the Government. *See Grubbs*, 565 F.3d at 190; *Huron Consulting Grp.*, 2011 WL 253259, at *2. The amended complaint meets that standard. It alleges with particularity a kickback scheme whereby Novartis paid doctors honoraria for

participating in sham speaker programs to induce them to write prescriptions for Novartis drugs, Am Compl. ¶¶ 1-2, 95-149; it identifies specific doctors who received honoraria in connection with sham speaker programs, *id.* ¶¶ 153-54, 157; it shows that those specific doctors not only wrote prescriptions for Novartis drugs after they began receiving honoraria (or significantly increased levels of honoraria) in connection with the drugs, but also that they significantly increased their levels of prescription writing during that period, *id.*; and it shows that those specific doctors wrote a substantial number of prescriptions for Novartis drugs after they began receiving honoraria (or significantly increased levels of honoraria) that were paid for by federal programs, *id.* ¶ 176. The Government's pleading is not "piecemeal," Def. Ltr. 2; it shows that the same doctors who participated in the kickback scheme thereafter wrote prescriptions for Novartis drugs that were paid for by the Government. These allegations support the required inference that the fraudulent scheme resulted in claims tainted by kickbacks being submitted to the Government. *See U.S. ex rel. Simpson v. Bayer Corp.*, No. 05-3895, 2013 WL 4710587, at *13-*14 (D.N.J. Aug. 30, 2013) (to survive a motion to dismiss, it is sufficient to allege an "illegal kickback scheme engineered to induce medical providers to prescribe [particular drugs], which would inevitably cause false claims to be submitted to the government"; a plaintiff "need not identify a particular false claim submitted to the government").

Novartis's assertion that the increase in the doctors' prescribing habits could have been due to factors other than the kickbacks, *see* Def. Ltr. 2, is immaterial. To establish a violation of the FCA predicated on kickbacks, the Government need only show that Novartis knowingly provided doctors with honoraria to induce them to write prescriptions for drugs that were reimbursable under federal programs, and that the doctors thereafter wrote prescriptions that were in fact paid for by a federal program. *See* 42 U.S.C. § 1320a-7b(b)(2), (g); *U.S. ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295, 313 (3d Cir. 2011). There is no requirement that the Government also prove the negative — that the prescriptions would not have been written absent the kickbacks — just as there is no requirement that the Government prove that the sole purpose of the kickbacks was to induce prescription writing. *See U.S. v. McLatchey*, 217 F.3d 823, 834-35 (10th Cir. 2000) (to establish an AKS violation, plaintiff need only show that "one purpose" of the kickback was to induce referrals). And even if there were such a requirement, it would not be something that the Government would have to plead for purposes of satisfying Rule 9(b). *See Bayer Corp.*, 2013 WL 4710587, at *14; *see also United Health Group*, 659 F.3d at 313 ("[T]o survive a Rule 12(b)(6) motion, [plaintiff] need not allege a relationship between the alleged AKS violations and the claims [defendant] submitted to the Government. Rather, [a complaint is sufficient if plaintiff] plead[s] that [defendant] knowingly violated the AKS while submitting claims for payment to the Government . . . .").

Third, the Government has sufficiently alleged fraud in connection with each of the drugs at issue in the amended complaint. *Cf.* Def. Ltr. 2-3. The Government has identified 15 doctors whom it alleges wrote prescriptions that were unlawfully induced by honoraria, and it has shown that during the period that those 15 doctors received honoraria (or significantly increased levels of honoraria), they wrote prescriptions for each of the relevant drugs. Am. Compl. ¶¶ 151-58, 176 & Exs. A-O.[1] The Government has also alleged — and provided specific examples to show

[1] The Government is not seeking to recover for prescriptions that are covered by the 2010 settlement between Novartis and the Government. *Cf.* Def. Ltr. 3 n.1. To the extent any

— that doctors who received honoraria from Novartis in connection with certain of its drugs were more likely to write prescriptions not just for those drugs but for Novartis drugs in general. *See id.* ¶ 158 (alleging that one of the 15 doctors "was more inclined to prescribe Diovan over comparable drugs in part because of his status as a speaker on Lotrel"). For Lotrel, Valturna and Starlix, the Government has gone one step further — and beyond what is required under Rule 9(b) — and shown that numerous doctors substantially increased their prescription writing for one or more of those drugs during the period they received honoraria (or significantly increased levels of honoraria) in connection with the drug(s). *Id.* ¶¶ 151-57. While the amended complaint includes more examples of doctors who increased their prescription writing for Lotrel than for Valturna or Starlix, *see* Def. Ltr. 2-3, that is because Novartis held many more speaker programs (and paid much more in honoraria) in connection with Lotrel than the other drugs. Am. Compl. ¶ 71 (29,000 programs and $51 million for Lotrel; 6,500 programs and $11 million for Valturna; and 3,200 programs and $4 million for Starlix).

Finally, the Government has provided sufficient allegations of sham speaker programs to support its claim of a far-reaching fraudulent scheme. *Cf.* Def. Ltr. 3. As set forth above, the Government has provided examples of sham speaker programs that took place across the country, and involved upwards of 50 doctors.

2. There Is No Deficiency Regarding the Unjust Enrichment Claim

The Government has alleged that Novartis paid kickbacks to doctors that induced the doctors to write prescriptions for its drugs, and that Novartis ultimately received payments from federal programs in connection with those unlawfully induced prescriptions. Am. Compl. ¶¶ 1-3, 192. Such allegations provide a sufficient basis for the Government's unjust enrichment claim, and the Government may pursue that claim as an alternative theory of liability. *See U.S. v. Stevens*, 605 F. Supp. 2d 863, 870 (W.D. Ky. 2008); *U.S. v. United Techs. Corp.*, 255 F. Supp. 2d 779, 785 (S.D. Ohio 2003).

3. The Government May Pursue Medicaid Claims Arising Prior to 2010

Novartis argues that, prior to the passage of the Patient Protection and Affordable Care Act ("PPACA") in 2010, the certifications submitted in connection with Medicaid claims were insufficient to state a claim under the FCA. Def. Ltr. 4. The PPACA provides that "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]." 42 U.S.C. § 1320a-7b(g). However, this provision was intended merely to clarify that all claims resulting from illegal kickbacks are considered false claims for purposes of civil actions under the FCA. *See* 155 Cong. Rec. S10853-54. Indeed, prior to the passage of the PPACA, courts frequently found that compliance with the AKS was a condition of payment and that an AKS violation could, therefore, serve as a predicate for FCA liability, including for Medicaid claims. *See, e.g., U.S. v. Rogan*, 517 F.3d 449, 452 (7th Cir. 2008) (affirming FCA judgment based on violation of AKS involving Medicare and Medicaid billings); *U.S. ex rel. McNutt v. Haleyville Med. Supplies*, 423 F.3d 1256, 1259-60

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such prescriptions were included in the exhibits attached to the amended complaint, it was an oversight.

(11th Cir. 2005) (imposing FCA liability based on violation of AKS). Moreover, *Mikes v. Straus*, 274 F.3d 687, 696-702 (2d Cir. 2001), which Novartis cites, is no impediment, as (a) it does not involve an alleged violation of the AKS; (b) it addresses only a single theory of liability — which here is an alternative theory of liability — based on "express" or "implied" certifications; and in any event, (c) the claims for payment here in fact violate both express and implied certifications of compliance with the AKS, and thus satisfy the standard set forth in *Mikes*.

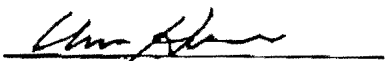
4. Discovery Should Not Be Stayed Pending Resolution of Novartis's Motion to Dismiss

"[D]iscovery should not be routinely stayed simply on the basis that a motion to dismiss has been filed." *Moran v. Flaherty*, No. 92-3200, 1992 WL 276913, at *1 (S.D.N.Y. Sept. 25, 1992). In deciding whether to stay discovery, courts consider, among other things, "the strength of the motion." *Brooks v. Macy's, Inc.*, No. 10-5304, 2010 WL 5297756, at *2 (S.D.N.Y. Dec. 21, 2010); *accord Hong Leong Fin. Ltd. v. Pinnacle Performance Ltd.*, No. 12-6010, 2013 WL 2247794, at *3 (S.D.N.Y. May 22, 2013). A motion to dismiss must have "substantial grounds" to justify a stay of discovery. *Hong Leong Fin. Ltd.*, 2013 WL 2247794, at *3.

Here, Novartis's proposed motion to dismiss does not have "substantial grounds." At the July 18, 2013 conference, the Court commented that the initial complaint "contain[ed] substantial details about the alleged kickback scheme." Tr. 18. While the Court did raise concerns about whether the Government had alleged (a) a sufficient link between the alleged kickback scheme and the payment of tainted claims by the Government and (b) sufficient detail about the relevant claims and claims process, the Government has since addressed those concerns. Its amended complaint includes a detailed description of the relevant claims and claims process, as well as specific examples supporting the requisite strong inference that doctors who participated in the kickback scheme were induced to write prescriptions for Novartis drugs that were ultimately paid for by the Government. Novartis's Rule 9(b) arguments are thus insubstantial, as are its peripheral arguments regarding the Government's unjust enrichment and pre-2010 Medicaid claims. Having failed to propose a motion to dismiss that is likely to succeed, Novartis's request to stay discovery should be denied. *See Ass'n Fe Y Allegria v. Republic of Ecuador*, No. 98-8650, 1999 WL 147716, at *1 (S.D.N.Y. Mar. 16, 1999).

Respectfully,

PREET BHARARA
United States Attorney

By: 

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